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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,249	12/17/2001	Manuel Vega	37851-911	7196

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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,249	VEGA ET AL.	
	Examiner	Art Unit	
	Channing S Mahatan	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 42-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 and 42-44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8 Sheets</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

APPLICANTS' ELECTION

Applicants' election without traverse of Group I (claims 1-33; drawn to a process for the production of a polypeptide having a predetermined property) in the reply filed on 30 July 2004 is acknowledged.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-33 and 42-44. Claims 34-41 have been cancelled.

Provisional Obviousness-Type Double Patenting

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §

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3.73(b).

Claims 1, 5-9, and 27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 13, 14, 17, and 18 of copending Application No. 10/375,192. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the broadly encompassing scope of the instantly claimed invention making the inventions to have overlapping embodiments. For instance, the instant applications encompass a process for the production of a molecule (i.e. peptide, polypeptide, protein) having a predetermined property, wherein the steps comprise: 1) producing a population of sets of target functional nucleic acid molecules that each comprise a target modified functional sequence of nucleotides (i.e. encode modified forms of a target protein); 2) introducing each set of nucleic acid molecules into host cells and expressing a protein whose expression is modulated or regulated by the target functional sequence of nucleotides (i.e. encoded protein), wherein the host cells are present in an addressable collection (i.e. array); and 3) individually screening the sets of encoded proteins to identify the target functional nucleic acid molecules (i.e. encoded protein) whose activity is altered (i.e. differs), wherein each such target functional nucleic acid is designated a hit. Therefore, the aforementioned claims in the instant application and issued patents encompass overlapping embodiments.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 1-33 are indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states that it is “A process for the production of a peptide, polypeptide, or protein having a predetermined property...”. The claim recites a final step of “individually screening the sets of encoded proteins to identify one or more proteins that have activity that differs from the target protein, wherein each such protein is designated a hit”. There is no indication that a “peptide, polypeptide, or protein having a predetermined property” is intended to be produced as recited in the preamble. While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. The claim does not set forth the conditions/state when a peptide, polypeptide, or protein having a predetermined property is produced. Further, it is unclear if the “activity that differs from the target protein” in the identification of one or more proteins (modified form of the target protein) is the intended to be the activity of the “predetermined property” or some other activity which is to differ between the modified form of the target protein and the target protein. Clarification of the metes and bounds of the claim is requested, via clearer claim wording.

Claims 1, 9, and all claims dependent therefrom recite the limitation “to identify one or more proteins that have activity that differs from the target protein” which is considered vague

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and indefinite. It is unclear what Applicants' intend the language "activity" to encompass such that an individual can identify an activity of the modified target protein to differ from that of the target protein. Applicants can resolve this issue by particularly pointing out what the Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 16 recites the limitation "replacing each codon that is a hit, with a codon encoding the remaining amino acids" which is considered vague and indefinite. It is unclear if Applicants' intend such replacement to be from: 1) a list of remaining amino acids without the amino acids of the "codon that is a hit"; or 2) from the remaining amino acids within the peptide/polypeptide/protein; or 3) both. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 17 recites the language "optimized lead" which is considered vague and indefinite. The above language implies a set of criteria(s)/parameter(s) that is indicative of an "optimized lead" which is unclear. Applicants' can resolve this issue by particularly pointing these set of criteria(s)/parameter(s). Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 19-21, 25, and 26 recite the term "effected" which is considered vague and indefinite. It is unclear what Applicants intend effected to encompass. For instance, what defines "recombining" to be "effected by a method selected from among nucleic acid shuffling, recombination, site-directed or random mutagenesis and de novo synthesis" (claim 19)? What defines "modifications" to be "effected in a selected domain of the target protein" (claim 20)? Etc?

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Claims 24-26 recite the limitation “at step (b) the titer of the viral vectors in each set of cells is assessed” which is considered vague and indefinite. It is unclear what Applicants intend this step(s) to provide to the instantly claimed invention, since the claimed invention does not utilize this assessed information. If the claimed invention is to utilize this information in, for example, “individually screening...” the claims are not representative of this. Clarification of the metes and bounds, via clearer claim language, is requested.

LACK OF ANTECEDENT BASIS

Claim 16 recites the limitation “codon that is a hit”. However, claims 1 and 9 (which claim 16 depends from) fails to indicate the identification of a “codon that is a hit”. It is acknowledged that claims 1 and 9 do indicate hits per se, but do not indicate a “codon that is a hit”. Thus, there is insufficient antecedent basis for this limitation in the claim.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-23, 27, and 42-44 are rejected under 35 U.S.C. § 102(e) as being anticipated by Short (U.S. Patent Number 6,171,820 B1).

Short discloses a method of producing a set of mutagenized progeny polynucleotides encoding a polypeptide from a parental template polynucleotide (i.e. target protein), via “codon

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site-saturation mutagenesis", wherein at each original codon position there is produced at least one substitute codon encoding each of the 20 naturally encoded amino acids (claims 1, 2, 4, 9-12, and 19-21; Abstract; Column 1, lines 32-42; Column 5, lines 12-33; and Columns 33-35, beginning on line 51). Figure 2 illustrates the use of the site-saturation mutagenesis approach for achieving all possible amino acid changes at each amino acid site along the polypeptide (codon mutagenesis (N,N,G/T); claims 13-15 and 42-44; Column 6, lines 47-60). Example 5 describes the screening of the progeny where the mutagenized polynucleotides encoding polypeptides were introduced (i.e. plasmid, viral vector, etc) into host cell (i.e. bacterial) on an addressable array (i.e. well plate, loci, etc) and analyzed for kinetic activities (improved stability) (claims 3, 5-8, 16-18, 22, 23, and 27; Column 11, lines 38-46; Column 20, lines 51-58; and Columns 55-56, beginning on line 34). The inventor also provides the optional repeating of the described steps (Column 5, lines 8-11). Thus, Short anticipates the instantly claimed invention.

OBJECTION TO DISCLOSURE

The disclosure is objected to because of the following typographical errors:

- 1) "nInternational" should be replaced with "International" (page 4, lines 13).
- 2) "PCT n^o" should be deleted (page 4, line 21 and page 6, line 2)
- 3) "mehods that adapt"" should be replaced with "methods that adapt" (page 8, line 24).
- 4) "Gen ration of" should be replaced with "Generation of" (page 30, line 3).
- 5) "disc very f protein variants at th amino" should be replaced with "discovery of protein variants at the amino" (page 31, lines 1-2).

Applicants' cooperation is requested in correcting any additional errors that Applicants may become aware in the specification.

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Appropriate correction is required.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify Applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables Applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Examiner Initials: *CSM*

Date: *October 13, 2004*

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
10/14/04
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